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Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane (HFA-305
Rockville, MD 20852

RE: Docket 99N-4784
Proposed Rule: Premarket Notification: Requirement for Redacted Version of Substantially Equivalent Premarket Notification

I applaud FDA's intention to facilitate the disbursement of releaseable 510(k)s while at the same time protecting an applicant's confidential information contained within its premarket notification submission. However, as written, the proposed rule ill serves that goal and does not correct the present intolerable situation.

CURRENT PROBLEM

The CDRH Freedom of Information office has 7 officers to handle all FOIA requests. (This is CDRH's own figure.) Due to the sheer volume of requests, a 510(k) FOIA request waits inline, on the shelve, for approximately 12 months before ever being looked at. Then it takes another 12 months for FDA and the 510(k) holder to negotiate what may or may not be released. In section C, 64 FR page 71348; December 21, 1999, you refer to the "tight statutory time frames FDA faces for responding to FOIA requests." The statutory time frame might be tight, but the reality is quite different. FDA has skirted the issue of a timely response to requests by sending an acknowledgment and control number letter to the requester, and counting this acknowledgment letter as fulfilling the statutory requirements. Knowing that it takes at least 2 years to receive a redacted 510(k) has effectively curtailed the number of requests. It is understandable that large manufacturers would like to keep it this way.

DOES THE PROPOSAL SOLVE THE PROBLEM?

I do not believe that the proposed rule corrects the current problem, but creates more difficulties and poses many unanswered questions. In Section B, 64 FR page 71348; you state that current regulations "obligate a firm to provide a copy of an appropriately redacted 510(k) to any requestor." Although there are many companies who attempt to fulfill this requirement in a diligent manner, there are also many who ignore the request or "string" it along for many months. I would hesitate to support any proposed rule which allows the total responsibility of 510(k) redaction to rest solely with the sponsor. It is FDA's responsibility to protect the public

99N-4784

C16

and secure the information that under statute should be in the public domain. How will the requester know when excessive redactive abuse has taken place? What is FDA's time frame for handling complaints from the requestor? What mechanism does FDA envision to deal with disputes? Will that mechanism need statutory approval?

FDA states that one of the benefits of allowing the applicant to redact their own 510(k) is that the applicant would have a "larger voice in determining what information would be protected from disclosure." The problem for this reader is that the 510(k) applicant wouldn't just have a larger voice in the process, but in fact, be the only voice. As noted in B. Implementation and Enforcement 64 FR page 71350, "FDA would not routinely review each redacted 510(k)...FDA will rely on parties that request 510(k) to raise issues of excessive redaction." Even though FDA states that it retains exclusive authority to make final determinations and is not delegating this authority to the 510(k) sponsors, it clearly will not act in the public interest unless asked to do so by a requestor. How does a requestor determine whether he has a legitimate claim? At what point does the requestor come to FDA and says he has a problem?

ALTERNATIVE PROPOSAL

Currently, FDA spends approximately one year communciating with manufacturers in order to arrive at a mutually statisfactory redacted 510(k). Clearly, manufacturers have had a large voice in determining what is confidential and what is releasable. In II Procedural Amendments, 64 FR page 1348, FDA proposes to allow a 30 day grace period between the actual 510(k) clearance and the submission of a redacted public version. FDA believes that " it is significantly easier and less expensive...to deal with FOIA disclosure issues an at early stage rather than having to reassemble experts..." I agree, and therefore suggest that manufacturers submit a redacted 510(k) as part of the whole 510(k) application process. The benefits, as stated by FDA are even more applicable when applied to co-mingling the approval and redaction process. The team is already assembled, both FDA reviewers and sponsors are familar with the application and able to recognize what is confidential or conversely releaseable. To meet a 30 day timeframe, the manufacturer would have to begin his redacted version before final approval, so this suggestion is not as onerous as it appears. Also it would allow for FDA to maintain it's final authority and not turn the requestor into a reviewer or government agent which is patently illegal.

Also, given that many 510(k)s are several hundred pages, I suggest that FDA not post every redacted 510(k) on the web. But rather post a list of those available, stating how many pages it is. A requestor can submit an individual request, with his billing information (as Medline does), and it can then be downloaded. The requestor will be billed the same way FOIA requestors are now billed.

Thank you for this opportunity to address this complex issue.

Sincerely,

Shawna Brandeberg